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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.
09/284,697	07/06/99	GRUBER	V 855-15

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EXAMINER

EINSMANN, J

ART UNIT	PAPER NUMBER
1655	13

DATE MAILED: 03/22/01

Please find below and/or attached an Office communication concerning this application or proceeding.

Commissioner of Patents and Trademarks

Office Action Summary

Application No.

09/284,697

Applicant(s)

GRUBER ET AL.

Examiner

Juliet C. Einsmann

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136 (a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 4/19/99, 11/16/00, 2/20/01.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 27-56 is/are pending in the application.
- 4a) Of the above claim(s) 29,30,36-38 and 42-56 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 27,28,31-35 and 39-41 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claims _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are objected to by the Examiner.
- 11) ☐ The proposed drawing correction filed on _____ is: a) ☐ approved b) ☐ disapproved.
- 12) ☐ The oath or declaration is objected to by the Examiner.

Priority under 35 U.S.C. § 119

- 13) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.
- 14) ☐ Acknowledgement is made of a claim for domestic priority under 35 U.S.C. § 119(e).

Attachment(s)

- 15) ☒ Notice of References Cited (PTO-892)
- 16) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 17) ☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____
- 18) ☐ Interview Summary (PTO-413) Paper No(s). _____
- 19) ☐ Notice of Informal Patent Application (PTO-152)
- 20) ☒ Other: Raw Sequence Listing Error Report.

DETAILED ACTION

1. Preliminary amendments filed 19 April 1999, 16 November 2000, and 20 February 2001 have been entered. Claims 1-26 have been cancelled and claims 27-56 have been added. Claims 27-56 are pending.
2. The references in the file (as cited on the PCT search report) have been considered. However, it is noted that no 1449 has been submitted listing these references.

Election/Restrictions

3. Applicant's election without traverse of Group I in Paper No. 12 is acknowledged. Upon further consideration, the claims to host cells (claim 32) and plants (claims 39-41) have been rejoined with the products and methods for expression of Group I. Claims 27-28, 31-35, and 39-41 are examined herein.
4. It is noted that the elected claims contain subject matter drawn to more than one invention. As a proper response to this office action, the claims must be amended to cancel non-elected subject matter.

Specification

5. The spacing of the lines of the specification is such as to make reading and entry of amendments difficult. New application papers with lines double spaced on good quality paper are required.
6. This application contains sequence disclosures that are encompassed by the definitions for nucleotide and/or amino acid sequences set forth in 37 CFR 1.821(a)(1) and (a)(2). However, this application fails to comply with the requirements of 37 CFR 1.821 through 1.825 for the following reason(s): The computer readable form submitted 16 November 2000 has errors (see

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attached raw sequence listing error report). In order to comply with the requirements of the sequence rules (37 CFR 1.821 - 1.825), Applicant must submit a new CRF and a letter stating that the content of the paper and computer readable copies are the same.

7. The amendment filed 16 November 2000 is objected to under 35 U.S.C. 132 because it introduces new matter into the disclosure. 35 U.S.C. 132 states that no amendment shall introduce new matter into the disclosure of the invention. The added material which is not supported by the original disclosure is as follows: The full length sequences of human lipase and human colipase, SEQ ID NO: 15 and SEQ ID NO: 16, respectively, in the sequence listing. No basis for the inclusion of these full length sequences was identified in specification as filed or in the WO or French priority documents.

Applicant is required to cancel the new matter in the reply to this Office Action.

8. The disclosure is objected to because of the following informalities:

(A) This application does not contain an abstract of the disclosure as required by 37 CFR 1.72(b). An abstract on a separate sheet is required.

(B) Page 66 of the specification as originally filed has some text written in French.

Appropriate correction is required.

Claim Rejections - 35 USC § 103

9. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

10. Claims 27-28, 31-35, 39-41 are rejected under 35 U.S.C. 103(a) as being unpatentable over Willmitzer *et al.* (WO 92/01042) in view of Lowe *et al.* (J. of Biological Chemistry, 1989, 264 (33): 20042-20048).

Willmitzer *et al.* teach transgenic plants expressing industrial enzymes, and methods for the production of such plants. The industrial enzymes suggested by Willmitzer *et al.* for use in these methods include lipases (p. 6, line 21). They specifically teach that the DNA sequence encoding the enzyme of interest should be under the control of a promoter such as the 35s RNA promoter from cauliflower mosaic virus (p. 4, lines 28-29) and a terminator such as the 35s RNA terminator from cauliflower mosaic virus (p. 5, line 18). Willmitzer *et al.* further suggest that the expression constructs include a DNA sequence encoding a leader peptide capable of directing the transport of the expressed enzyme to a specific cellular compartment (for example vacuoles) (p. 5, lines 22-25). Willmitzer *et al.* teach a variety of plants useful for the introduction of the enzyme, including tobacco, potato, tomato, pea, soy, and cereals (p. 7, lines 19-21), and further teach that either the entire plant or parts thereof may be useful for animal feeds (p. 7, lines 10-13). Willmitzer *et al.* teach vectors for the integration of foreign DNA into plant cells and the introduction of these vectors into *Agrobacterium* species (p. 9, line 28-p. 9, line 19). Willmitzer *et al.* further teach methods for the recovery of the transgenic enzymes, and such method steps include an extraction step (p. 12, lines 8-16).

Willmitzer *et al.* do not exemplify these methods with a pancreatic lipase.

Lowe *et al.* teach recombinant nucleic acids coding for human pancreatic lipase (Fig. 2).

It would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made to have inserted the coding sequence taught by Lowe *et al.* into a plant using

the methods taught by Willmitzer *et al.* The ordinary practitioner would have been motivated to express a nucleic acid encoding a lipase in a plant as taught by Willmitzer *et al.* because Willmitzer *et al.* expressly teach that the production of enzymes in plants overcomes two major obstacles in industrial enzyme production, "Firstly, higher plants have biosynthetic capacity to perform the requisite post-translational modifications occurring in eukaryotic cells of mammalian or other origin. Secondly, transgenic plants grown in the field need very little extra energy for growth (and hence for the production of proteins such as industrial enzymes) and furthermore do not give rise to any major problems with respect to waste management (p. 4, lines 10-18)." Willmitzer *et al.* provide the necessary suggestion and direction to motivate the production of lipases in plants, and thus, in the absence secondary considerations such as unexpected results, the claimed invention is obvious over the prior art.

Conclusion

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11. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Juliet C. Einsmann whose telephone number is (703) 306-5824.

The examiner can normally be reached on Monday through Thursday, 7:00 AM to 4:30 PM.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, W. Gary Jones can be reached on (703) 308-1152. The fax phone numbers for the organization where this application or proceeding is assigned are (703) 308-4242 and (703) 305-3014.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (703) 308-0196.


JEFFREY FREDMAN
PRIMARY EXAMINER


Juliet C. Einsmann
Examiner
Art Unit 1655

March 16, 2001